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RESEARCH

Improvement noted after a multifaceted approach to diabetes mellitus management

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Background: Optimal control of diabetes mellitus remains elusive, especially in developing countries. A comprehensive and standardised approach, coupled with intensive patient and clinician education, may provide the solution.

Methods: Comprehensive datasheets accompanied by patient education from a multidisciplinary team and clinician retraining on diabetes management was introduced into the Edendale Hospital diabetes clinic in 2012. This study compares diabetes control starting October 1, 2012 to September 30, 2013 (Y1) to October 1, 2013 to September 30, 2014 (Y2).

Results: Significant changes (p-values < 0.005) were noted in the following parameters between Y2 and Y1 respectively:

- * Mean HbA1c% (10.41 \pm 2.91 vs. 11.26 \pm 2.99).
- * Mean HbA1c in males (9.46 vs. 10.57) and (10.38 vs. 11.19) for females.
- * Mean HbA1c for type 1 (11.80 vs.10.77) and type 2 patients (10.91 vs.10.10).
- * Percentage of patients achieving triglyceride control (64.28 vs. 52.85).
- * Percentage of patients making lifestyle changes and performing home glucose monitoring.
- * Increase in female waist circumference (97.29 vs. 85.95 cm).
- * Increase in BMI in males (29.65 vs. 27.92 kg/m²).

Conclusion: This multifaceted approach to diabetes care in a resource-limited clinic significantly improved glycaemic and triglyceride control. Obesity remains a major challenge. This model could serve as a blueprint for other such resource-limited clinics.

Introduction

Approximately 22 million people are now living with diabetes mellitus (DM) in Africa with a staggering 62% of cases in Africa being undiagnosed.¹

Optimal control of DM is essential to prevent complications and is an important goal. ^{2,3} Studies performed in both the private and public health sectors have revealed that we are not achieving optimal control of this disease. ⁴⁻⁶ The first year of data collected from the diabetic clinic at Edendale Hospital in Pietermaritzburg, KwaZulu-Natal revealed that blood pressure, lipid and glycaemic control was suboptimal. ⁴ Edendale hospital is a busy regional-level hospital situated in the uMgungundlovu district of Pietermaritzburg in the province of KwaZulu-Natal.

Pollard et al.⁷ showed that electronic patient registries do improve some outcomes (HbA1C, LDL, total cholesterol) in resource-limited diabetes clinics. Ricci-Cabello et al.⁸ proposed that, in order to improve diabetes care in resource-limited diabetes clinics, multiple intervention strategies need to be directed towards both the attending clinicians and patients. Involving a multidisciplinary team allows the primary clinician to spend more time on clinical assessment and assigns patient education to the team.^{9,10} Clinical inertia may account for one of the reasons for overall poor diabetes control in our clinics.¹¹ Igbojiaku et al.¹² in their study conducted at a regional hospital in KwaZulu-Natal found that clinicians demonstrated poor adherence to diabetes guidelines. Poor compliance with diabetes guidelines by clinicians was also noted in other studies carried out in the United States of America and in Norway.^{13,14}

Taking all the above into consideration (patient registries, multiple intervention strategies, clinical inertia and poor adherence to clinical guidelines by clinicians) our intervention had a multifaceted approach targeting both the health providers and the diabetes patient.

Our study assessed the effect on clinical and biochemical outcomes after the cumulative introduction of the following interventions between year 1 (Y1) and year 2 (Y2):

- a paper-based diabetic data sheet to ensure standardisation of management of all patients seen at the Edendale hospital diabetic clinic. Development of a specially designed computer program based on the datasheet to capture all data and to aid in analyses of data via crystal generated reports:
- re-training of all clinicians working at the clinic on diabetes care according to the latest South African guidelines;
- a multidisciplinary team (emphasis on patient education in lifestyle modification [diet and exercise], self home blood glucose monitoring, regular clinic visits, foot care, annual eye assessments).

Y1 encompassed the period from October 1, 2012 to September 30, 2013 while Y2 included the period from October 1, 2013 to September 30, 2014. This is a retrospective data review study that was approved by UMgungundlovu Health Ethics Review (UHERB) and the Biomedical Research Ethics Committee (BREC).

Methods

Prior to September 2012 all patients seen at the Edendale Hospital diabetes clinic were seen by clinicians without any specific parameters (i.e. the clinician assessed patients and made clinical and treatment decisions independently). This system changed to a more structured one in September 2012 where all patients who were seen at the diabetic clinic had a paper-based data sheet completed as part of their assessment. This datasheet included variables based on a comprehensive examination of the patient. The datasheet ensured the following:

- An up-to-date clinical record of each patient (including patient's epidemiology, comorbid conditions, lifestyle factors including diet, exercise, smoking and alcohol intake, physical examination, current prescription, latest blood results, ophthalmological review, electrocardiograph findings and podiatrist and dietician review).
- That the assessment of all diabetes patients seen in the clinic was standardised and comprehensive.
- That the clinicians were reminded of ophthalmological and electrocardiograph assessments, regular foot examinations and blood examinations as proposed by local diabetes guidelines.
- That there was dissemination of patient medical information to their local clinics or healthcare professional. Each sheet was completed in triplicate and one copy was affixed to patient's outpatient file and a second copy was given to patient. The third copy was sent for data collection onto the database.

All doctors working in the clinic were trained using the 2012 South African diabetes guidelines on the appropriate approach (history, clinical examination, investigations and pharmacological management) to diabetes patients. These guidelines were available in each of the consulting rooms for ease of access. Nursing staff were re-trained on the correct techniques for recording blood pressures, waist circumferences, height, weight and urine dipstick readings.

The data were captured manually onto a customised computer program, which was designed using Visual Basic.net® and .net technologies. The necessary reports for the study were generated from this specialised program using Crystal® reporting.

A multidisciplinary team became fully operational after the first year and included the following members:

- specialist physician/endocrinologist;
- · family physician;
- · medical officers;
- interns;
- podiatrist (for six-monthly foot examinations);
- dietician (for six-monthly dietary education);
- ophthalmologist (for annual vision and fundi examination);
- diabetic nurse educator (for every visit to clinic);
- nursing staff.

Patients were seen a minimum of twice a year but additional visits were scheduled for those patients with poor glycaemic control.

Patients were questioned at every clinic visit as to whether they were following a diabetic diet and exercise regimen as per local diabetes guidelines. The majority of patients in the clinic were not performing self-monitoring of blood glucose (SMBG) so for this

study SMBG was defined as positive if a patient had access to a glucometer and had had the necessary training on its use.

For this study we compared and contrasted Y1 with Y2 data to assess if the introduction of a multi-faceted approach to diabetes care (data collection tools, re-training of clinicians/nursing staff and a fully operational multidisciplinary team) made a difference in outcomes in the following parameters:

- (1) glycaemic control (HbA1c %);
- (2) blood pressure (BP) (in mmHg);
- (3) Lipids (total cholesterol and triglycerides)(in mmol/l).
- (4) Anthropometry:
 - · weight (in kg);
 - · waist circumference (in cm);
 - waist-to-height ratio (WTHR);
 - body mass index (kg/m²).
- (5) Lifestyle modification:
 - (a) diet;
 - (b) exercise;
 - (c) SMBG.

Results

Epidemiology

Of the 653 first-time patients to this new data capturing system seen during Y1 at the clinic, 403 patients of these patients were followed up during Y2. Only patients who were followed up in Y2 were employed for the necessary comparisons. These 403 patients accounted for the study population and had a female preponderance (76.67%). There was a greater number of Type 2 versus Type 1 diabetic patients (341 vs. 62, respectively) and the average duration of DM was 8.69 years. One and hundred and twelve (27.79%) of the 403 patients were HIV-infected.

Glycaemic control

The overall mean HbA1c% achieved in all 403 patients seen in Y1 versus Y2 was $11.26 \pm \text{standard}$ deviation (SD) $2.99 \text{ vs.} 10.41 \pm 2.91$, respectively, (p-value = 0.000, Wilcoxon signed rank tests). Table 1 illustrates the relationships observed between the types of DM, gender and mean HbA1c for both Y1 and Y2.

There was no significant difference, but a beneficial trend was noted in the number and percentage of patients achieving optimal glycaemic control (defined as HbA1c \leq 7%) between Y1 versus Y2 (53 (13.15%) vs. 69 (17.12%), respectively, p-value=0.089)) (McNemar test).

Blood pressure (BP)

The mean sitting BP achieved in Y1 was 139/83 mm Hg compared with 139/81 mm Hg in Y2. A trend was noted of a larger number and percentage of patients achieving target BP (defined as BP \leq 140/80 mm Hg \leq 130/80 mm Hg in Y2 when compared with Y1 (147 (36.48%) vs. 123 (30.52%), respectively, *p*-value = 0.097) (McNemar test).

Lipids (total cholesterol and triglycerides)

Table 2 illustrates mean cholesterol and triglycerides achieved for Y1 compared with Y2.

Anthropometry

Table 3 illustrates the relationships between weight, waist

Table 1: Relationship between HbA1c and gender and types of DM

Item	Mean H	Mean HbA1c %		Tests used
	Y1	Y2	_	
Males	10.57	9.46	0.001	Wilcoxon rank sign test
Females	11.19	10.38	0.000	Wilcoxon rank sign test
Type 1 DM	11.80	10.77	0.000	McNemar test
Type 2 DM	10.91	10.10	0.000	McNemar test

Table 2: Lipid control over Y1 and Y2

Item	Y1	Y2	<i>p</i> -value	Test used
Mean cholesterol (mmol/l)	4.18	4.10	0.386	Wilcoxon rank sign
Mean triglycerides (mmol/l)	1.97	1.61	0.000	Wilcoxon rank sign
Number and percentage of patients that achieved target cholesterol (≤4.5 mmol/l)	249 (61.79%)	261 (64.76%)	0.303	McNemar
Number and percentage of patients that achieved target triglyceride (≤1.7 mmol/l)	213 (52.85%)	259 (64.28%)	0.000	McNemar

Table 3: Anthropometry comparisons for Y1 and Y2

Item	Males		<i>p</i> -value	Females		<i>p</i> -value	Statistical test
-	Y1	Y2		Y1	Y2		used
Weight (kg)	79.65	82.54	0.240	80.92	78.37	0.432	Wilcoxon
BMI (kg/m²)	27.92	29.65	0.026	33.19	32.20	0.800	Wilcoxon
Waist circumfer- ence (cm)	83.97	95.68	0.781	85.95	97.29	0.004	Wilcoxon
Number and percentage of pa- tients with waist circumference > 86 cm in males and > 92 cm in females	60 (14.89%)	71 (17.62%)	0.999	201 (49.88%)	238 (59.05%)	0.108	McNemar
Number and percentage of patients with WTHR > 0.5	37 (9.18%)	42 (10.42%)	0.774	173 (42.93%)	161 (39.95%)	0.067	McNemar

circumference, waist-to-height ratio (WTHR) and body mass index (BMI) in males and females when compared with Y1 and Y2. Our data also suggest that obesity remains a global challenge.

Lifestyle modifications

Table 4 illustrates the changing picture noted with regard to lifestyle between Y1 and Y2. There were significant improvements

Table 4: Lifestyle modification

Modification	Number and percentage o	Number and percentage of patients compliant with:		Test used
	Y1	Y2		
(a) Diet	311 (77.17%)	338 (83.87%)	0.012	McNemar
(b) Exercise	188 (46.65%)	251 (62.28%)	0.000	McNemar
(c) SMBG	116 (28.78%)	167 (41.44%)	0.000	McNemar

Table 5: Differences in body composition with and without lifestyle modification in Y1 and Y2

Item	Year 1			Year 2		
	With lifestyle modification	Without lifestyle modification	<i>p</i> -value	With lifestyle modification	Without lifestyle modification	<i>p</i> -value
Mean BMI (kg/m²)	32.45 ± 8.69	33.90 ± 8.77	0.021 (ANOVA)	32.36±7.43	34.08±7.81	0.029 (ANOVA)
Number of patients with WTHR > 0.5	86/162 (53.1%)	127/241 (52.7%)	1.000 (Fisher's exact test)	111/227 (48.9%)	92/176 (52.3%)	0.547 (Fisher's exact test)

observed in Y2 with the performance of both exercise and SMBG when compared with Y1.

When lifestyle modification was defined using the total number of patients who were complaint with *both* a diabetic diet and an exercise regimen the following was observed:

- The number of patients observing lifestyle modification increased significantly between Y1 and Y2 (162 vs. 227, respectively, *p* < 0.000) (Fisher's exact test).
- Table 5 demonstrates that patients who followed lifestyle modification had significantly better mean BMI in both Y1 and Y2.

Discussion

The interest in the prevention and management of non-communicable diseases (NCDs) has peaked recently as they are the leading cause of mortality globally.¹⁵ DM is increasing at an alarming rate worldwide and up to 62.5% of diabetes sufferers in Africa are undiagnosed.¹ Long-term complications from diabetes can be prevented or delayed by better control of blood glucose and of blood pressure.³ Thus far we have noted from other studies that we are not achieving this control either in state hospitals or in the private sector in South Africa.^{4–6} DM with its complications places a large economic burden on countries, especially in developing countries where there is an additional burden of infectious diseases.

This study assessed the effect that the introduction of a multifaceted approach to diabetes care had on both clinical and biochemical outcomes in a regional-level hospital diabetic clinic in South Africa. This multifaceted approach encompassed the creation of a multidisciplinary team within the diabetic clinic, coupled with intensive patient education and clinician re-training on SEMDSA guidelines on diabetes management. A data collection tool was specifically designed and introduced into the clinic in conjunction with the changes already noted. This tool comprised both a paper-based diabetes datasheet and a specially designed computer program in which to capture all data collected from the datasheets.

The results from this study showed that overall glycaemic control had significantly improved in Y2 compared with Y1. This significant improvement in glycaemic control was found in both type 1 and type 2 diabetic patients and in both male and female patients. The UKPDS study demonstrated that, irrespective of baseline HbA1c, a 1% decrease in HbA1C translates into a 10% reduction in diabetes-related mortality and a 37% decrease in microvascular complications.3 The significant reductions in the HbA1c observed in our patients in Y2 would therefore translate into lower longterm diabetic complications and a decrease in diabetes-related mortality. A larger percentage of patients in Y2 achieved target glycaemic control when compared with Y1. Although this represents an improvement with our multifaceted intervention in achieving target HbA1c in Y2 it also implies that a significant percentage of the diabetic patients are still not achieving optimal diabetic control. However, this still represents an upward trend when compared with optimal HbA1c achieved in a previous study conducted at the same clinic by Pillay et al., which showed that only 12.4% of diabetic patients achieved optimal glycaemic control.4

Blood pressures did not differ significantly between Y1 and Y2. However, there was a beneficial trend in the percentage of patients in Y2 achieving optimal BP control when compared with Y1. BP control is essential for diabetes control and the UKPDS study showed that BP control is more important than glycaemic control to avoid long-term complications.³ Coupled with the glycaemic control seen with our study this trend of improved BP control in these patients in Y2 is promising. Future studies within the diabetic-hypertensive patient population should focus on optimising control of blood pressure by following published hypertension guidelines.

Significant decrease in serum triglycerides was observed in Y2 compared with Y1. This improvement could be attributed to the improved glycaemic control together with increased adherence to dietary guidelines noted in our study. A significant improvement was noted in the percentage of patients achieving target triglyceride levels in Y2 compared with Y1. No difference in mean cholesterol levels was observed between Y2 and Y1. The percentage of patients achieving target cholesterol levels was no better in Y2 compared with Y1.

Obesity remains a global modifiable factor when striving for optimal diabetes control, especially in South Africa where obesity rates are the highest in sub-Saharan Africa.¹ Our study demonstrated that obesity remains a persistent problem and is increasing despite improvements noted with regard to diet and exercise in our study. BMI increased in males between Y1 and Y2 while in females BMI remained in the obese range between Y1 and Y2. The weight gain noted could possibly be explained by the intensive nature of this study where increasing doses of insulin were used to optimise glycaemic control. Obesity remains a challenge that needs to be addressed comprehensively to enable clinicians to achieve optimal diabetes control.

What was evident from our study was that with the introduction of comprehensive care and patient education from all levels of the multidisciplinary team there can be statistically significant increases in compliance with lifestyle modifications (diet, exercise and SMBG all increased) between Y1 and Y2. Lifestyle remains an integral component of managing DM and preventing complications. Patients who followed both a diabetic diet and an exercise regimen had significantly better BMIs when compared with their counterparts who failed to adhere to both a diet and exercise regimen. Our approach to lifestyle modifications in a regional-level clinic proves that there is definite merit in patient education coupled with standardised and comprehensive care from a multidisciplinary team.

We set about this study to improve patient registries, clinical inertia and poor adherence to clinical guidelines by clinicians by using multiple intervention strategies. Success of the above strategies is reflected in the overall results of our study, which show significant improvements in glycaemic and triglyceride control together with increases in number of patients achieving target blood pressures and total cholesterol levels. Overall the number of patients following a diet, exercise regimen and performing SMBG all increased significantly.

Conclusion

In South Africa, most DM is diagnosed and managed at a primary care clinic level and these clinics are often resource-limited. This study demonstrates that simple basic interventions like the introduction of a comprehensive data sheet that allows for standardisation of diabetic management together with a multidisciplinary team coupled with patient and clinician education has merits in improving glycaemic, BP and triglyceride control. Control of these three parameters is fundamental in

achieving optimal diabetes care, which translates into fewer long-term complications and decreases the burden on both the patient and the country's health care system as a whole.

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